

In re Application of:  
Serial No.:  
Atty. Docket No.:

Nelson  
09/024,988  
530-005

Art Group:  
Examiner:

1642  
Ungar, Susan

## REMARKS

### *Claim Status*

Claims 31, 33, 40, and 41 have been rejected. Claim 41 has been canceled. Therefore, claims 31, 33, and 40 are pending in the instant application.

### *Declaration*

A substitute declaration, signed by all inventors is submitted herein, as per the examiner's request.

### *Claim Rejections - 35 U.S.C. § 112*

Claims 40 and 41 have been rejected according to reasons set forth in the previous office action Section 4, page 3. The applicant has canceled claim 41 and amended claim 40 as per the examiner's suggestion to overcome the section 112 rejection. Therefore, the applicant respectfully requests that the examiner withdraw the instant rejection.

Claims 31, 33, 40 and 41 have been rejected according to reasons set forth in the previous office action Section 4, page 3. The examiner is unsure why (IRS) is included in parenthesis and requests citation to the specification for support of the limitation that the affinity reagent captures the analyte and IRS and simultaneously isolates them from the contents remaining in the specimen.

As the applicant's attorney discussed over the telephone, the parenthesis around IRS service to identify a shortened reference form for the phrase "internal reference standard". The examiner concurred and agreed to withdraw the instant rejection.

Support for the position that the affinity reagent captures the analyte and IRS and simultaneously isolates them from the contents remaining in the specimen may be found on page 25, lines 1-5; page 25, first full paragraph at mid-point;

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Further, in order to enable the instant application to proceed to issuance, the applicant has amended the claims as per the examiner's suggestion, thereby removing any indefiniteness.

Therefore, the applicant respectfully requests that the examiner withdraw the instant rejection.

***Claim Rejections - 35 U.S.C. § 103***

Claims 31, 33, 40, and 41 have been rejected for the reasons previously set forth in the previous office action, section 6, pages 4-7. The applicant's attorney and the examiner discussed these reasons telephonically, as evidenced an Interview summary written by the examiner. The examiner has agreed to withdraw the instant rejection and consider the above amendments to the claims, said amendments made to place the claims in position for allowance. The applicant respectfully requests that the examiner allow the claims as now amended and allow the claims.

The applicant requests that the examiner contact the applicant's attorney if there are any questions about the above amendments and/or wording in order to advance this matter to issuance.

Respectfully submitted,

Date: 6/17/01



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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage paid, in an envelope addressed to: Box Fee Amendment, Assistant Commission for Patents, Washington, D.C. 20231

on 8/17/01

By: K. H. Hall

**Version with Markings to Show Changes Made**

In the Claims:

Please cancel claim 41

Please amend the claims as follows:

Claim 31 (Once Amended) A method for quantifying an analyte in a specimen, said method comprising the steps of:

- d) combining said specimen with an internal reference species (IRS) of known concentration, in order to calibrate all subsequent steps; whereby said combination is referred to as an IRS-containing specimen;
- e) combining said IRS-containing specimen with an affinity reagent,  
*ANALYTE except it has been*  
capturing and isolating said analyte and said IRS, wherein said IRS is a  
*identical to said MODIFIED to have a*  
modified analyte with shifted molecular weight, which binds to said  
affinity reagent], wherein said capturing and isolating step comprises a substep of combining said IRS-containing specimen with an affinity reagent];
- f) quantifying said analyte wherein [in which said] quantifying [step] comprises using mass spectrometric analysis to resolve distinct signals for said analyte and said IRS to determine the ratio of the analyte signal to the IRS signal.

Claim 33 A method according to claim 31, in which said quantifying step further comprises [using] working curve analysis.

Claim 40 A method according to claim 33, in which said working curve analysis comprises substeps of:

- h) making a plurality of standard preparations, each containing a known but differing concentration of the analyte and each containing a known concentration of <sup>the</sup> IRS; [obtaining a first mass spectrum of a first portion of said IRS-containing specimen; then,]
- i) obtaining respective mass spectra of each of the plurality of standard preparations; [making a plurality of standard preparations each containing a known but differing amount of said analyte or a counterpart thereof and each containing a known or equal amount of said IRS; then, obtaining respective mass spectra of each of said plurality of standard preparations; whereby said respective mass spectra of said plurality of said standard preparations provide a working curve relationship of mass spectra relative to analyte concentration; and then,]
- j) normalizing each of the mass spectra from the plurality of standard preparations by dividing each <sup>analyte</sup> mass spectrum by the IRS signal within the mass spectrum; [using said first mass spectrum and the standard preparation mass spectra working curve relationship to quantify said analyte.]
- k) creating a working curve by equating the normalized analyte signals to the analyte concentration of the plurality of standard preparations;
- l) obtaining a mass spectrum for the IRS-containing specimen;
- m) normalizing the mass spectrum of the IRS-containing specimen by dividing by the IRS signal within the mass spectrum; and

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- n) quantifying the concentration of the analyte in the specimen using the working curve.

Claim 41 (Canceled)